

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**SeQuent Neo**PTCA-Katheter
(Artikelnummern siehe Anlage)mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang II, II.4
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse III / Regel 6**Benannte Stelle**
TÜV SÜD Product Service GmbH (ID-Nr. 0123)
Ridlerstraße 65, 80339 München, Deutschland**Ausgestellte Bescheinigung(en):**
G1 012974 0608 Rev. 00
G7 012974 0603 Rev.02**Datum der ersten CE-Kennzeichnung**
2013-07-23**Gültig bis**
2024-02-27

Berlin, 2020-05-19

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein
Head of Quality Management CoE VShereby declare in our own responsibility
that the product/s**SeQuent Neo**PTCA-Catheter
(article numbers see attachment)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex II, II.4
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class III / Rule 6**Notified Body**
TÜV SÜD Product Service GmbH (ID-No. 0123)
Ridlerstraße 65, 80339 Munich, Germany**Certificate(s) issued:**
G1 012974 0608 Rev. 00
G7 012974 0603 Rev.02**Date of first CE-marking**
2013-07-23**Valid until**
2024-02-27

Berlin, 2020-05-19

B. Braun Melsungen AG

i. V.

Dr. H. Schlicht
Head of Regulatory Affairs

Anlage I / Attachment I

Art.-Nr. / REF No.¹	Art.-Nr. / REF No.²	Artikelbezeichnung / Article description	Klasse / Class
5021711	5021711D	SeQuent Neo 1.25 x 10 mm	III
5021712	5021712D	SeQuent Neo 1.5 x 10 mm	III
5021713	5021713D	SeQuent Neo 2.0 x 10 mm	III
5021714	5021714D	SeQuent Neo 2.25 x 10 mm	III
5021715	5021715D	SeQuent Neo 2.5 x 10 mm	III
5021716	5021716D	SeQuent Neo 2.75 x 10 mm	III
5021717	5021717D	SeQuent Neo 3.0 x 10 mm	III
5021718	5021718D	SeQuent Neo 3.5 x 10 mm	III
5021719	5021719D	SeQuent Neo 4.0 x 10 mm	III
5021721	5021721D	SeQuent Neo 1.25 x 15 mm	III
5021722	5021722D	SeQuent Neo 1.5 x 15 mm	III
5021723	5021723D	SeQuent Neo 2.0 x 15 mm	III
5021724	5021724D	SeQuent Neo 2.25 x 15 mm	III
5021725	5021725D	SeQuent Neo 2.5 x 15 mm	III
5021726	5021726D	SeQuent Neo 2.75 x 15 mm	III
5021727	5021727D	SeQuent Neo 3.0 x 15 mm	III
5021728	5021728D	SeQuent Neo 3.5 x 15 mm	III
5021729	5021729D	SeQuent Neo 4.0 x 15 mm	III
5021731	5021731D	SeQuent Neo 1.25 x 20 mm	III
5021732	5021732D	SeQuent Neo 1.5 x 20 mm	III
5021733	5021733D	SeQuent Neo 2.0 x 20 mm	III
5021734	5021734D	SeQuent Neo 2.25 x 20 mm	III
5021735	5021735D	SeQuent Neo 2.5 x 20 mm	III
5021736	5021736D	SeQuent Neo 2.75 x 20 mm	III
5021737	5021737D	SeQuent Neo 3.0 x 20 mm	III
5021738	5021738D	SeQuent Neo 3.5 x 20 mm	III
5021739	5021739D	SeQuent Neo 4.0 x 20 mm	III
5021743	5021743D	SeQuent Neo 2.0 x 25 mm	III
5021744	5021744D	SeQuent Neo 2.25 x 25 mm	III
5021745	5021745D	SeQuent Neo 2.5 x 25 mm	III
5021746	5021746D	SeQuent Neo 2.75 x 25 mm	III
5021747	5021747D	SeQuent Neo 3.0 x 25 mm	III
5021748	5021748D	SeQuent Neo 3.5 x 25 mm	III
5021749	5021749D	SeQuent Neo 4.0 x 25 mm	III
5021753	5021753D	SeQuent Neo 2.0 x 30 mm	III
5021754	5021754D	SeQuent Neo 2.25 x 30 mm	III

¹ Manufacturing at B. Braun Melsungen AG, Vascular Systems Berlin, Germany. Date of CE mark: 2013-07-23

² Manufacturing at Aesculap Chifa Sp. z o. o., Poland. Date of CE mark of article numbers with Suffix D: 2019-07-15

Art.-Nr. / REF No.¹	Art.-Nr. / REF No.²	Artikelbezeichnung / Article description	Klasse / Class
5021755	5021755D	SeQuent Neo 2.5 x 30 mm	III
5021756	5021756D	SeQuent Neo 2.75 x 30 mm	III
5021757	5021757D	SeQuent Neo 3.0 x 30 mm	III
5021758	5021758D	SeQuent Neo 3.5 x 30 mm	III
5021759	5021759D	SeQuent Neo 4.0 x 30 mm	III

Title: SeQuent Neo_39.05.658_DOC Initiator: Annesha ? Lahiri

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Lahiri, Annesha (lahiande)
Title: Regulatory Affairs Manager
Date: Wednesday, 12 May 2021, 11:54 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Schlicht, Henning (schlhgde)
Title: Head of Regulatory Affairs
Date: Wednesday, 12 May 2021, 14:35 W. Europe Daylight Time
Meaning: Approve Document
